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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,022	11/25/2003	Mary Ann Lukas-Laskey	04012.0384	3995

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/721,022

Applicant(s)

LUKAS-LASKEY ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/875603.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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Applicants' Preliminary Amendment, Consent of Assignee, Power of Attorney and Statement under 37 CFR 3.73(b) and Reissue Declaration under 37 CFR 1.172 and 1.175 all filed June 18, 2004 are acknowledged. Claims 1-11 were allowed in US Patent 5,902,821. New claims 12-30 are presented. Claims 1-30 are now under consideration.

All references cited in the parent application must be cited on a PTO Form 1449 in the present application.

The reissue oath/declaration filed with this application is defective because the error that is relied upon to support the reissue application is not an error upon which a reissue can be based. See 37 CFR 1.175(a)(1) and MPEP § 1414.

Claims 1-30 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defects in the declaration is set forth in the discussion above in this Office Action.

Applicants state in paragraph 8 that U.S. Patent is at least partially inoperative or invalid by reason of the patentees claiming more or less than they had a right to claim.

In view of a filing date of the present application that is greater than two years, broadening of the claims is impermissible.

In paragraph 9 of the declaration Applicants state the error upon which reissue is based is the failure in the claims of the U.S. Patent 5,902,821 to recite administering to

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a patient third dosages comprising carvedilol daily for a maintenance period “to decrease a risk of mortality caused by congestive heart failure.”

The preamble already states “decreasing mortality”. The error recited would only be a semantic altering of the wording already in the preamble.

Since mortality is absolute, Applicants may consider claim language directed to reducing the occurrence of mortality from congestive heart failure.

Further, benefit under 35 U.S.C. 119(a) of DE 195 03 995 having a foreign application priority date of February 8, 1985 is noted. Correction is required.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most of the recited limitations in the claims, does not reasonably provide enablement for “said maintenance period is greater than six months” in relation to administration of third dosages. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants’ Table of Exemplary Support for the claim amendments and the new claims on pages 7-8 of the Preliminary Amendment has been carefully reviewed. The limitation added in claim 1 relating to the third dosages, “said maintenance period is greater than six months”, lacks clear support. In column 5 a maintenance dose is set forth that follows two earlier periods of treatment, but no time period for administration is given. In column 7, lines 56-57, a six to 12 month maintenance period is given, but is not directly related to the maintenance dosage. None of the examples exemplifies or clarifies this limitation.

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Claims 1, 7, 10, 20 and 26 recite no period of time for administration of carvedilol or fail to recite an upper limit in terms of the time period for treatment.

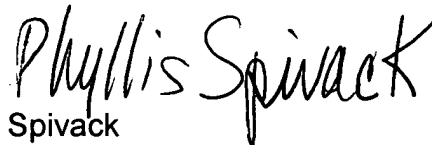
The claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614



**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**

January 7, 2004